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MEMORANDUM

October 9, 2003

BY ELECTRONIC MAIL

FROM: Olsson, Frank and Weeda, P.C.

RE: Prior Notice of Imported Food – FDA Interim Final Rule

The Food and Drug Administration (FDA) has issued its interim final rule requiring that importers or purchasers submit notice to FDA prior to importing or offering for import any food into the United States. The rule is expected to publish in the Federal Register on October 10, 2003. The rule in a [prepublished format](#) is available from the FDA website and at the following link:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/cf0356.pdf>

The interim final rule, together with the [final rule requiring registration of food facilities](#) (*see* our accompanying memorandum and <http://www.fda.gov/OHRMS/DOCKETS/98fr/cf0354.pdf>), are the first two of four rules implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). The Bioterrorism Act was passed in response to the events of September 11, 2001, and Title III of the Bioterrorism Act includes provisions designed to protect the U.S. food supply from acts of bioterrorism or intentional contamination.

This memorandum briefly summarizes the prior notice interim final rule and the many changes it will have upon the importation of food. A more detailed memorandum will follow shortly.

The prior notice interim final rule will affect the importation of all food products, including food ingredients, dietary supplements, fresh produce, alcoholic beverages, fish and seafood, animal feed products, including pet food, and live animals to be processed into food. **The prior notice interim final regulation is effective beginning December 12, 2003.** On that date, all articles of food offered for import into the United States will not be permitted to enter the United States unless they are covered by an adequate prior notice.

The prior notice interim final rule is vastly different from the proposed rule FDA issued in February. 68 Fed. Reg. 5428 (Feb. 3, 2003). Most significantly, and unlike the proposed rule, the prior notice interim final rule integrates with existing notification procedures importers now follow when reporting their food imports through FDA's Operational and Administrative System for Import Support (OASIS) system and the Bureau of Customs and Border Protections (Customs) Automated Broker Interface (ABI) of the Automated Commercial System (ACS). The time by which prior notice must be provided to FDA is also significantly shortened from the period set out in the proposed rule.

While effective on December 12, 2003, these interim final regulations may change. FDA is accepting comments from interested persons for the next 75 days. In March 2004, the agency will reopen the comment period on the regulations for an additional 30 days and then issue final regulations. During this time, FDA intends to emphasize educating industry about the new requirements. Except in the event of a health threat, FDA is not expected to begin strictly enforcing the prior notice regulations until after it has issued final regulations.

Summary Of The Prior Notice Interim Final Rule

The key features of the prior notice interim final regulations are:

- Anyone with knowledge of the required information may submit the prior notice, including, but not limited to, brokers, importers, and U.S. agents.
- Prior notice must be received and confirmed electronically by FDA no more than 5 days before arrival and, before the following time, depending upon mode of transportation:
 - 2 hours before arrival by road.
 - 4 hours before arrival by air or by rail.
 - 8 hours before arrival by water.
 - Before mailing if food is sent by international mail.
- The prior notice must be submitted to FDA electronically. The notice may be submitted through the ABI/ACS interface by a customs broker or through FDA's new FDA Prior Notice (PN) System Interface at www.access.fda.gov.
- The prior notice must contain the following information:
 - The submitter, including name, telephone and fax numbers, email address, and firm name and address.
 - The transmitter (if different from the submitter).

- Entry type and CBP identifier.
- The article of food, including complete FDA product code, the common or usual name or market name, the *estimated* quantity described from the smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable).
- The manufacturer.
- The grower, if known.
- The FDA “Country of Production.”
- The shipper, except for food imported by international mail.
- The country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed.
- The anticipated arrival information (location, date, and time) or, if the food is imported by international mail, the U.S. recipient (name and address).
- The importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States.
- The carrier and mode of transportation, except for food imported by international mail.
- Planned shipment information, except for food imported by international mail.
- If any of the following required information changes after confirmation of filing the prior notice, then a new prior notice must be submitted:
 - The submitter or transmitter.
 - Entry type and CBP identifier.
 - The article of food, except the estimated quantity.
 - The manufacturer, grower, shipper, importer, owner, or consignee.
 - The FDA Country of Production.

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- The country from which the article of food is shipped or, for food imported by international mail, the anticipated date of mailing.
- The U.S. recipient (name and address) if the food is imported by international mail.
- The carrier and mode of transportation.
- Planned shipment information unless the food will not be imported.

A detailed memorandum describing this lengthy rule will be available shortly. If you have any questions, please contact Tish Pahl at 202-789-1212, or tpahl@ofwlaw.com.

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